UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNIVERSITY OF SOUTH FLORIDA
RESEARCH FOUNDATION, INC.,

Plaintiff,

Case No. 3:18-CV-0250-K

vs.

BRIT SYSTEMS, INC.,

Defendant.
_____/

PLAINTIFF'S OPENING *MARKMAN* CLAIM CONSTRUCTION BRIEF

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Pursuant to the Court's Scheduling Order (as amended), Misc. Order No. 62, ¶ 4-5 (as modified), and N.D. Tex. L. Civ. R. 7.1(i) and 7.2 (as modified), Plaintiff University of South Florida Research Foundation, Inc. ("USFRF"), hereby submits its Opening Claim Construction Brief concerning certain claim terms of U.S. Patent No. 6,630,937 ("the '937 Patent").[1] In this case, USFRF alleges that Claims 1-3, 5-6, 8, 13-15 and 17 of the '937 Patent are infringed by Defendant BRIT Systems, Inc. ("BRIT" or "Defendant") through its manufacture, use, offer for sale and/or sale of its BRIT VISION, BRIT PACS VIEW and Mammography Module products.[2]

I. INTRODUCTION

Collectively, the parties have identified twenty-five (25) claim terms in the '937 Patent that require construction by the Court. Of the twenty-five terms, twenty-four (24) were identified by the Defendant in a blatant attempt to manufacture flawed non-infringement arguments, and avoid compensating USFRF for its long running infringement. Defendant ignores legal standards governing claim construction, discussed *infra* in Section IV of this Brief by isolating individual terms from the remainder of the claim in the hopes the Court will not appreciate their true contextual meaning. Defendant contends remaining terms are indefinite despite their meanings being well known to those of a person ordinary skill in the art ("POSA.") Defendant also asserts that certain means-plus-function ("M+F") claim terms are indefinite despite clear disclosure of both structure and an algorithm in the specification.

Conversely, USFRF submits that the claims use well known terms that are understood by POSAs, and that only a single claim term (Term 11) requires construction. Term 11 includes many of the individual terms that Defendant seeks to take out of context and makes clear that a key feature of the system of the '937 Patent claims is the ability to uniquely manipulate digitized

[1] A copy of the '937 Patent is attached as App.1-19.
[2] Although USFRF originally asserted infringement of all 17 Claims – and still does – USFRF voluntarily reduced the number of claims at issue to 10 to reduce the issues for the Court.

medical images, particularly digitized mammogram images. Term 11 also makes clear that the medical image data received by the claimed systems can originate from any form or digitization process so long is has the same images quality as x-ray films. Put simply, USFRF's invention broadly allowed for the complete replacement of x-ray films for clinical medical diagnosis, and the instant claims should be construed in the context of this pioneering advancement.

II. THE '937 PATENT REPRESENTS A SIGNIFICANT ADVANCE IN MEDICAL IMAGING THAT HAS PROVIDED REAL WORLD RESULTS

A. The Background of the Invention and Patent

The invention of the '937 Patent represents the significant efforts of a group of professors and researchers working at the University of South Florida's ("USF") Moffitt Cancer Center in Tampa, Florida in the mid-1990s. The group, headed by noted researchers Dr. Maria Kallergi and Dr. Laurence P. Clarke, sought to enhance a doctor's ability to quickly and more accurately diagnosis cancer than was possible by a radiologist reading an x-ray film. In an effort to improve on the then existing x-ray film-based diagnostic techniques, Drs. Kallergi and Clarke developed a novel and non-obvious system for clinical medical diagnostic workstations to display and manipulate digitized mammograms and other digitized medical images, allowing radiologists, other doctors, and clinicians to more accurately search for and find suspicious abnormalities, such as cancer cells. USF obtained the '937 Patent in October 2003 to protect the inventors' groundbreaking advancements. USF granted USFRF an exclusive license to the '937 Patent.[3]

After Moffitt Cancer Center received FDA approval for a commercial embodiment of the '937 Patent claims, virtually all companies in the digital imaging and mammography fields, including Defendant began manufacturing and selling digital imaging workstations that incorporated USF's digital imaging techniques. (App.71-85; App.86-90.) This system represents

[3] USFRF is the entity at the USF responsible for licensing and enforcing the '937 Patent.

a quantum leap in medical technologies, and its usage in diagnosis has helped decrease the mortality rate of women diagnosed with breast cancer by over 35%. (App.66-70.) The ACS attributes this decrease in breast cancer mortality to early detection techniques, which clearly includes the widespread use of the invention of the '937 Patent. (App.66-70.) Some of the best praise relative to the merits of the invention of '937 Patent came directly from BRIT itself. The ex-President of BRIT, and 30(b)(6) witness, Ms. Michelle Fisher, identified the following advantages of the invention over the previous clinical diagnostic systems that relied on x-ray films:

- Can be read "anywhere" and can be viewed simultaneously by multiple radiologists;
- As fast or faster than the use of film: no set up necessary;
- Facilitates easy comparison studies;
- Can make adjustments of the illumination and contrast;
- No retakes are necessary (as often needs to be done with x-ray film);
- Limits women's time being imaged;
- Can adjust the greyscale values and width of each image on the monitor separately, or in groups, or all at the same time;
- More accurate than x-ray films ("absolutely");
- Increased chance of finding possible cancer earlier; and
- Can be used with CAD systems to improve chances of finding cancer.

(App.81-85.)

B. Summary of the Patent Disclosure

In the mid-1990s, when the inventors conceived the invention of the '937 Patent, standard diagnostic techniques relied on the reading of images on x-ray films.[4] The inventive interface of the '937 Patent replicates standard mammography x-ray reading, but provides quicker and more accurate images that can be easily manipulated so radiologists can discover abnormalities earlier. (App.16, 4:48-54, 60-63; App.17, 6:42-53.)

FIG. 3

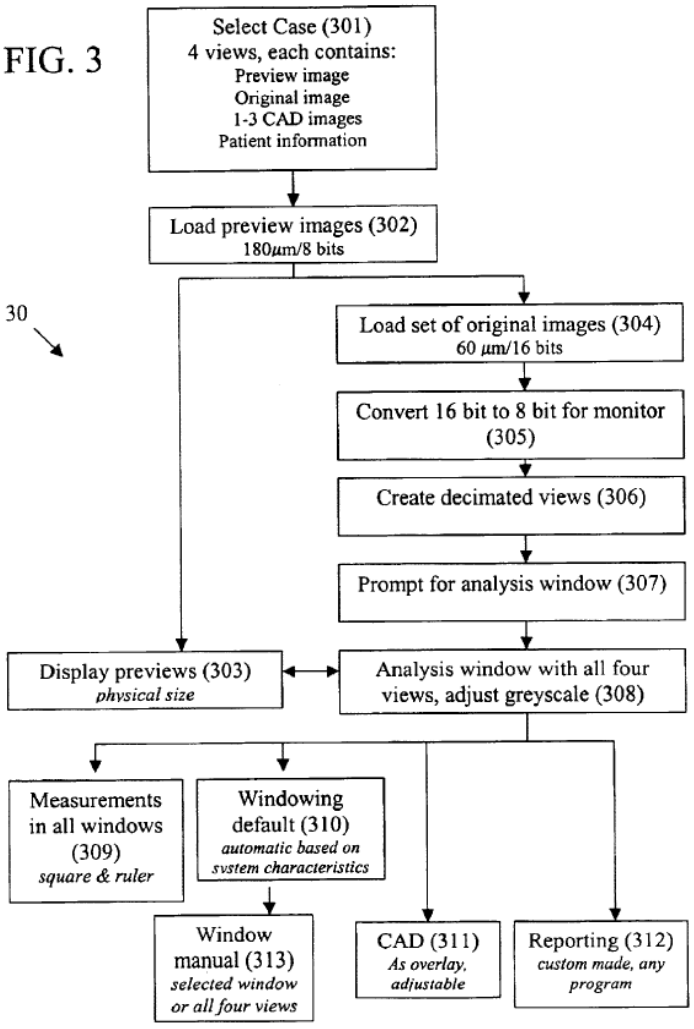


Figure 3 (shown on the left) is a flow chart (algorithm)[5] which along with along with its accompanying description disclose a series of processor-implemented steps for displaying and manipulating digitized medical images, including digitized mammogram images. (App.16-17, 4:62-5:51.) Figure 3 depicts several sub-algorithms, such as the algorithm of steps 304-308, which describe the step

[4] A typical medical mammogram "case" follows the "standard" four-view mammogram protocol used by radiologists. (App.17, 5:2-5.) (For simplicity, references to passages in the '937 Patent are expressed, for example, as "5:2-5" rather than "Column 5, lines 2-5.")

[5] Other algorithms relating to use of the system appear in the written description of the '937 Patent either alone or in combination with the drawings.

"for transforming the image into a plurality of varying resolution forms, each form having different greyscale values." (App.17, 5:39-51.)[6] Specifically, the exemplary algorithm for "transferring" (step 304) involves loading a set of four original views (left/right/CC and left/right ML) into the system. (App.17, 5:7-14.) These views can then be transformed (step 305) from a larger size ("16 bit") to a smaller size ("8 bit") so they contain fewer bytes of information (and thus are faster to display) and conform to the grayscale range of the monitors. (App.16, 4:15-26; App.17, 5:13-18.)

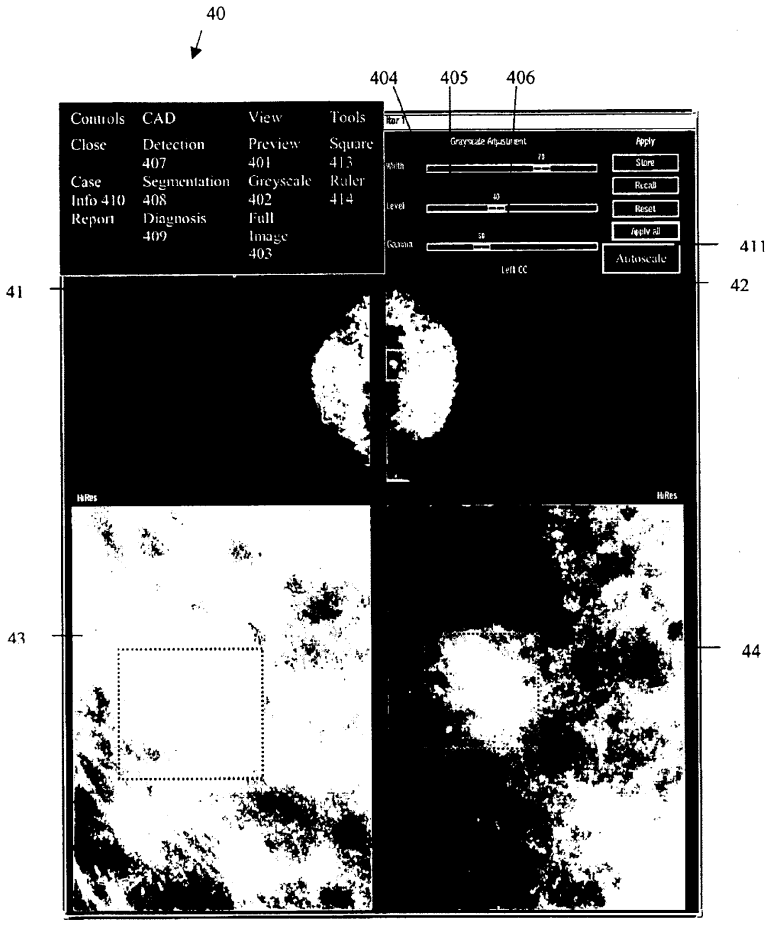
In step 306 of this transforming algorithm, the original view is "decimated" – changed to a smaller size and resolution. (App.17, 5:21-28.) This allows the entirety of the breast images to fit in a display window. (App.17, 5:25-28; App.156, ¶ 40.) The results of the image transforming algorithm may be seen in Figure 4 where windows 41 and 42 display the two CC views as decimated images. (App.17, 5:21-28.) As a result of this process, a "full image" can be displayed (as shown in Figure 6 window 61) for viewing by the radiologist upon "selecting a button on the control panel." (App.17, 5:52-53, Button 403.) The full image view in Figure 6, window 16, corresponds in size to one of the two full images of Figure 13.

After the decimated views are displayed in windows 41 and 42 (see Figure 4 below), the radiologist can clinically analyze the images and replace the global overview shown in window 40 with two CC views 41, 42 (steps 304, 305). (App.17, 5:15-18.) The radiologist then can use a mouse (input device) to point and click (referred to as a "prompt" in Figure 3: Step 307) to select an analysis window from the menu. (*See* App.5, FIG 4.) Thereafter, the radiologist can select an image area in window 41 (the small square in Figure 4 image below indicated by dotted lines in

[6] "Grayscale refers to pixel intensity "mapped into monitor luminance from black to white and all intermediary gray values in between." (*See* App.148, ¶ 20, App.151-152, ¶ 29.)

window 41) by selecting button 413 in the menu. A full resolution image can then be displayed in window 43, as shown in Figure 4. (App.17, 5:23-25.) Step 308 in the Figure 3 algorithm also discloses that all four views can be displayed for analysis at any time. (App.17, 5:21-28, 39-40.)

At that point, the Radiologist can vary the brightness, contrast, and resolution of the images displayed in each of the analysis windows in real time using a mouse 18. (App.17, 5:39-51.) Each of the four images can be viewed and manipulated one at a time, in groups, or all at the same time to look for abnormalities. (App.17, 5:39-49.) The adjustments can be accomplished by sliding the slide buttons 404, 405 and 406 (as shown in Figures 4-8) with the mouse. (App.17, 5:41-47; App.16, 4:66-5:2.) The "width" slide button 404 can vary the contrast of the window, the "level" slide button 405 can change the brightness (illumination) of the image, and the "gamma" slide button 406 can change the resolution of the images. (App.4, FIG 3, algorithms of Step 313; App.5, FIG 4; App.17, 5:39-51; App.151-153, ¶¶ 27-32; App.158, ¶ 46.)



Other algorithms of the invention are shown in the Figure 3 algorithm by Steps 309, 311, and 312. For example, the user can measure the size of the images in any of the windows (Step

309) by using the measuring square button 413 and ruler button 414 in Figure 4 and/or by using the 1 cm square in Figure 7, or the ruler 80 in Figure 8. (App.17, 6:46-54.) The user also can select the "Report" option 412 (Step 312) from the case selection window 40 (Figure 4) and secure what is shown in Figures 11 and 12. (App.18, 7:25-38.)

As clearly reflected in the specification and drawings, the '937 Patent provides a unique and convenient clinical diagnostic workstation interface, which replaces the hanging x-ray film viewing systems radiologists previously used, thereby producing a significant advancement for the medical field.

III. HISTORY OF THE CLAIMS AT ISSUE

The application that lead to the '937 Patent was filed on February 22, 2002, and claims priority to a provisional application 60/075,443, which discloses the claimed inventions, and which was filed on February 20, 1998. The '937 Patent is a continuation-in-part of another USFRF patent, U.S. No. 5,987,094 (the '094 Patent")[7] which also discloses digital imaging techniques. The '094 Patent has a common inventor (Dr. Clarke) and common owner (USFRF).

The United States Patent Office ("USPTO") allowed all 17 claims in the '937 Patent after considering prior art in view of the inventor's arguments regarding the novelty of the invention. In allowing the claims, the USPTO Examiner noted the novelty of the technology as, "mak[ing] the technology of digital mammogram easy to adopt to and thence successful when presenting the information to the radiologists effectively." **(**App.38-40.**)** The Examiner further noted that the prior art submitted failed to teach or suggest key limitations, including the ability to transform the data into varying resolution forms and then allowing for analysis and manipulation of those forms. (App.38-40.) Thus, having established the novelty of its invention, USFRF received the '937 Patent consisting of 17 claims. Asserted Claims 1, 2, 3, 6 and 17 are shown in their entirety

[7] A copy of the '094 Patent is attached as App.42-65.

in App.20-23 with the disputed non-means plus function terms emphasized.

IV. LEGAL STANDARDS APPLICABLE TO CLAIM CONSTRUCTIONS

The legal standards governing claim construction are well settled. Claim construction is a matter of law "exclusively within the providence of the court." *Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996). Additionally, the words of a claim are generally given their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e. as of the effective filing date of the patent application." *Phillips v. AWH Corp*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). "[T]he person of ordinary skill in the art is deemed to read the claim term not only in context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id*. at 1313.

Where "the ordinary meaning of a claim language as understood by a person of skill in the art [is] readily apparent even to lay judges, [ ] claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id*. at 1314. However, such clarity is not always the case. Where it is not, the Court must look to:

> those sources available to the public that show what a person of ordinary skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence . . .

Phillips, 415 F.3d at 1314 (internal quotations omitted).

A. Intrinsic Evidence

"It is well-settled that, in interpreting an asserted claim, courts should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification (drawings and written description) and, if in evidence, the prosecution history." *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[T]he claims themselves provide

substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. "To begin with, the context in which a term is used in the asserted claim can be highly instructive." *Id*. "The specification 'is always highly relevant to the claim construction analysis. Usually, it is the single best guide to the meaning of a disputed term.'" *Id*. at 1315 (quoting *Vitronics*, 90 F.3d at 1582.)

Patent specifications generally describe "preferred embodiments." However, the claims, not the embodiments of the specification, define the scope of patent protection. *Phillips*, 415 F.3d at 1323; *see also Johnson & Johnson Assoc. Inc. v. R. E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (*en banc*). Similarly, the claims are not to be construed to only cover the preferred embodiment or one of the disclosed embodiments. *SRI Intern. v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). As such, the claims are to be given their full scope to cover all embodiments and equivalents.

It is also to be noted that even though the parties provide two possible constructions for each of the terms in dispute, the Court can modify the proposed constructions or select another construction it feels is appropriate. *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995) "([T]he trial judge has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties.")

B. Extrinsic Evidence

Courts are also permitted to use extrinsic evidence, such as "expert and inventor testimony, dictionaries, and learned treatises" in claim construction. *Phillips*, 415 F3d at 1317. Expert testimony is useful to provide background on the technology at issue, explain an invention, ensure that the court's understanding of the patent is consistent with a POSAs, or establish that a term or the prior art has a particular meaning in the pertinent field.

For the Court's consideration, attached hereto as App.143-269 and App.270-361 are the

Declarations of Dr. Ehsan Samei ("Samei Declaration"), and the Declaration of Joseph C. McAlexander ("McAlexander Decl."), respectively. Dr. Samei is a Professor at Duke University and Head of the Radiology Department at the Duke Medical Center. He also worked in the digital medical imaging field for several decades. He is an expert in the digital imaging and radiology fields. The Samei Decl. provides background on the digital medical imaging field and the inventions of the '937 Patent. He also opines on the common and ordinary meaning of certain claim terms at issue based on his understanding as a POSA. Mr. Alexander is both an expert in computer and software technologies, and is as knowledgeable as to what POSAs in the digital medical imaging field now know and would have known as of the dates of conception and reduction to practice of the claims of the '937 Patent.. Mr. Alexander can point out the structure in the '937 Patent that support the claim terms, including all of the M+F terms.

V. THE COURT SHOULD ADOPT USFRF'S PROPOSED CONSTRUCTIONS WHICH COMPORT WITH THE INTRINSIC AND EXTRINSIC EVIDENCE AND APPLICABLE LAW

The parties have collectively identified eleven different claims terms they believe require construction. While the claim terms are numbered 1-11 to correspond to the Joint Claim Construction Statement, USFRF has grouped the terms for ease of analysis as follows: (a) claim preamble terms; (b) USFRF Universal Term; and (c) Defendant's individual isolated terms.

A. Preamble Terms

It is axiomatic that the language of a claim preamble is generally not considered limiting. *Apex Eyewear, Inc. v. Marchon Eyeware, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012). More specifically, "a preamble is not limiting, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Poly-America LP v. GSE Lining Tech. Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004); *see also Catalina Mktg., Int'l v. Coolsavings.com*, 289 F.3d 801, 808-09 (Fed. Cir. 2002) ("a

preamble generally is not limiting especially when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.").

Term 1: **"system for providing an interface"/"system for interfacing"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
No construction required. ***Alternatively,*** a computer system	System that facilitates interaction, communication or exchange of information between different components	Preamble of Claims 1, 2, and 3

The terms "system for providing an interface" and "system of interfacing" appear in the preambles of Claims 1, 2, and 3, and merely identifies the intended use for the structurally complete invention in the bodies of those claims. Removal of these terms within the preamble would not otherwise affect the scope or structure of the claim. *Catalina Mktg., Int'l.*, 289 F.3d at 808-09. Not only do these preamble terms not appear in the body of their claims – which would evidence that they could constitute structure and not solely an intended use – the patentee never relied on them as a distinguishing feature over the prior art during prosecution. Instead, the preamble uses the "system for…" terms only to state the intended use of the structurally complete components of the system that are located within Claims 1, 2 and 3, i.e., "processor," "means for communicating," "monitor," etc. (App.162, ¶ 59.) The body of Claims 1, 2, and 3 thus define completed inventions and the "system for providing and interface"/"system for interfacing" terms do not require any construction. (App.162, ¶ 59.)

If the Court believes that construing these terms would assist a jury, then USFRF's construction ("*a computer system*"), accurately reflects the stated purpose of the preamble.

Specifically, the interface system recited in the preamble is "a computer system," which allows a user to interact with a digitized mammogram. (App.162, ¶ 59.) This construction is supported by the specification, which repeatedly describes a computer-based interface system. (*See, e.g.,* App.2, Abstract ("A workstation-user interface for evaluating computer assisted diagnosis (CAD) methods for digital mammography is disclosed.")) Indeed, "[t]he hardware and software sections discuss the technology used for the implementation of the present invention in a way that would provide a user-friendly interface…" (App.16, 3:12-15; *see also* App.16, 3:28-50, 3:61-4:8, 4:34-35.) Additionally, Figure 3 is a, "flow chart showing the sequence of steps in implementing the workstation interface to display a case to a user." (App.15, 2:48-50.) The Court should reject Defendant's attempt to use Claims 1-3's preamble to impose unnecessary limitations that are not required by the claims.

Term 10: **"system for analyzing"**

Plaintiff's Proposed Construction	**Defendant's Proposed Construction**	**Claim(s) in which terms appear**
No construction required. ***Alternatively,*** a computer system that provides the capability to analyze digital mammogram images	System that facilitates a study or examination	Preamble of Claim 17

This term appears in the preamble of Claim 17. Like the terms discussed above, Defendant ignores Federal Circuit guidance and asserts this term requires a limiting construction. The "system for analyzing" recited in Claim 17's preamble merely provides for the intended use of the complete invention within the body of the claim; that complete invention includes, *inter alia*, monitors and a processor to display the images thereon. (App.19, 10:50-65.) Based on the legal authorities above, there is no reason legally or factually to construe Claim 17's preamble.

However, if the Court believes a construction is necessary to assist the jury, USFRF's construction should be used, as it provides a simple construction that is supported by the claim and the specification. The preamble of Claim 17 recites in pertinent part "a system for analyzing a set of digital mammography images . . . comprising." Similarly, the specification provides that "[a] significant issue in the development of the interface was the speed with which ***images are displayed and analysis is done.***" (App.17, 6:55-57 (emphasis added); *see also* App.17, 5:14-18, 5:21-27, and 5:39-51; App.16, 4:55-59, 4:62-63.) In other words, the preamble term "system for analyzing" refers to a computer system that provides the capability to analyze digital mammogram images. Conversely, the Defendant's proposed construction imports the unnecessary and improper limitations of study or examination that are not supported by the intrinsic evidence, and are added in an effort to impermissibly limit the proper scope of Claim 17. (App.165, ¶ 68.)

B. Universal Term

While Defendant insists that the Court construe three separate claims terms ("digitized mammogram data," "greyscale values," and "optical densities") isolated from the context of the claims as discussed below, USFRF submits that construing them as a single term in context will more readily help the jury with its role, and more accurately reflects their true meaning. Additionally, Defendant's construction of Terms 4 through 9 depend upon Defendant's erroneous construction of the term "grayscale values" and thus fails upon a rejection of its limiting construction thereof. Instead of construing individual terms in isolation, the Court can address these terms collectively as part of a combined Universal Term.

Term 11: **"the digitized mammogram data having greyscale values corresponding to optical densities of the film mammogram image"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
regardless of how the digital mammogram image is formed, i.e. from either direct digital or an x-ray film, the greyscale values of the image are substantially the same	the digitized images of the patient's breast having greyscale values that correspond to optical densities of the film images of the patient's breast	Claims 1 and 2

The above phrase is contained in Claims 1 and 2 and is part of the following claim limitation recited in full:

> means for receiving digitized mammogram data[8] corresponding to a film mammogram image, ***the digitized mammogram data having greyscale values corresponding to optical densities of the film mammogram image***

(App.18, 8:61-65, emphasis added.) The construction of this term is evident when it is read as a part of Claims 1 or 2. Specifically, the inventors developed a workstation interface for use in digital medical imaging, including digital mammography that improves clinical medical diagnostics over the then-standard use of x-ray film. (App.2, Abstract; App.15, 1:33-60, 2:13-30.) Use of prior techniques lacked the speed and accuracy provided for in the present invention. (App.81-85.)

To convert radiologists from the existing standard reading procedure, the inventors created a system which had the qualities and comforts of a film-based system, but the speed and accuracy of a digital system. (App.18, 7:41-55.) This included an interface that allowed users to view, analyze and manipulate digitized mammogram image data originating in a variety of forms, including x-ray film or direct digital data. (App.2, Abstract; App.14, 1:33-60, 2:13-30;

[8] Claim 2 recites "digitized mammogram image data" instead of "digitized mammogram data."

App.158-159, ¶¶ 47-49.) USFRF's proposed construction of this term, namely "*regardless of how the digital mammogram image is formed, i.e. either direct digital or an x-ray film, the greyscale values of the image are substantially the same,*" reflects this inventive contribution and is mandated by the intrinsic record. For example, the specification teaches "[i]t is another object [of the present invention] to provide such a workstation interface that is ***comparable to the existing standard reading procedure*** [i.e., film]." (App.15, 1:65-67, emphasis added; *see also*, App.162, ¶ 60.) Further, the interface was designed to depict the standard mammography viewbox reading while including all of the most intuitive assets of a digital display. (App.16, 4:48-50; s*ee also* App.16, 4:9-26, 4:36-46; App.17, 5:19-23.) Inclusion of the term "film" provides context for the state of the art at the time of the invention, but does not limit the invention to the use of a film image. (App.162, ¶ 60.)

Put simply, the reference to film mammography in Claims 1 and 2 merely requires that the claimed digital image data have qualities (i.e. greyscale values) that ***correspond*** to the qualities of optical densities of film images. (App.165-166, ¶ 69.) Indeed, the use of the phrase "correspond to a film mammogram image" in the claims makes this clear. Moreover, while the terms "greyscale values" and "optical densities" of the mammogram image data appear in the claims, it is only a reference to the image quality of the digitized data compared to the prior diagnostic methods that employ film. (App.162-163, ¶¶ 61, 62; App.165, ¶ 67; App.166, ¶ 69.) Nothing in the claims require that the digitized mammogram data be assigned a precise numerical values.

As indicated above, Defendant's proposed construction takes the terms out of context and impermissibly seeks to limit them to use of actual film images and specific numerical "grayscale values" and "optical densities" in order manufacture future non-infringement arguments. This is

erroneous and should be rejected. By construing the instant term, the Court can also avoid the piecemeal claim interpretations Defendant seeks below, and resolve the dispute quickly and efficiently in a manner that more accurately comports with the inventions of the '937 Patent.

C. Remaining Terms

Contrary to accepted claim construction principles, and to support erroneous limiting constructions, Defendant offers piecemeal constructions of various claim terms without considering the context of the remainder of claim language. *See Phillips*, 415 F.3d at 1314. As discussed above, the Court should avoid such a piecemeal and improper claim construction process by construing Term 11 above. However, out of an abundance of caution, USFRF has provided proper constructions for the individual terms listed below.

Term 2: **"digitized mammogram/digitized mammography image"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
No construction required. ***Alternatively,*** digital image presentations of a human breast	Image or images of a patient's breast or breasts that have been produced by digitizing film or films of the breast image(s)	Claims 1, 2, and 17[9]

Defendant's proposed construction imports words from the written description, knowingly and purposely taken out of context, into the claims so as to limit the meaning of "digitized mammogram data" to data digitized from a "film mammogram image" while at the same time ignoring the explicit language of the claims. Nothing in the written description supports Defendant's proposed construction. Nothing in the claims supports Defendant's proposed construction. Simply put, Defendant impermissibly ignores the explicit language of the

[9] With respect to Claim 17, "digitized mammography image" appears only in the preamble and is not limiting for the same reasons discussed above with respect to Terms 1 and 10.

claims in order to propose a claim construction Defendant believes would obviate infringement. Defendant's attempt to fool the Court with its disingenuous and dishonest proposal must fail.

Initially, the claim language – which is always the starting point for claim construction – supports USFRF's proposed construction. The relevant language of Claim 1 provides a, "means for ***receiving digitized mammogram data*** corresponding to a film mammogram image." (emphasis added.) The claim language does not recite, "is," "identical to," or otherwise place limits on where the digitized mammogram data originates. The data could originate from a film or any other method, like direct digital, which can produce a digitized image. (App.158-159, ¶¶ 47-49; App.58, 7:6-7.) Subsequent language in Claims 1 and 2 confirms that the data need only ***correspond*** to a film mammogram image. (App.18, 8:61-65; App.19, 9:21-26.) This is precisely what the inventor, Dr. Maria Kallergi, stated was the purpose and scope of the invention during her deposition.[10] Any limitation requiring images to be produced only by digitizing film would be completely contrary to her invention and in direct contradiction to the intrinsic evidence.[11] Put simply, the workface interface invention was conceived to ***eliminate*** the need to use film in clinical medical diagnostic examinations. (App.15, 2:14-21.)

The specification itself, makes clear that the claimed enable a digitized image reading process that is familiar to radiologists who previously used only analog x-ray film reading for clinical medical diagnostic examinations:

> The interface was designed to depict as closely as possible the standard mammography viewbox reading . . . (App.16, 4:48-49.)

[10] App.99-100. Dr. Kallergi's testimony was confirmed by co-inventor Dr. Himanshu Gohel at his deposition. (App.110.)

[11] Moreover, the '094 Patent, which is a parent to the '937 Patent and whose disclosure is incorporated by reference into the '937 Patent identifies other ways to arrive at the digital mammogram data "x-ray film digitizer" or by "direct digital x-ray sensors." (App.58, 7:6-7.)

> Such choices are believed to facilitate a clinician's making a smooth transition to the present system. (App.16, 4:51-52.)
>
> Commercial systems exist for several modalities that generate digital data including magnetic resonance imaging (MRI), computed tomography (CT), chest radiology, ultrasound, and nuclear medicine. (App.15, 1:53-57.)
>
> It is another object to provide a workstation interface that is comparable to the existing standard reading procedure. (App.15, 1:65-67.)

(*See also* App.15, 1:26-30, 1:33, 1:38, 2:13-30, 2:51-56; App.16, 3:22-26; App.5-14, Figs. 4-13.)

The Declaration of Dr. Ehsan Samei further highlights the error in Defendant's position. Dr. Samei opines that persons skilled in the art after reading the '937 Patent would understand the two "digitized mammogram" terms as simply referring to "digital image presentations of a human breast" unrestricted by the manner in which the image data originates. (App.162, ¶ 60.)

Conversely, Defendant's proposed construction improperly limits the terms to the disclosed embodiment. While the specification identifies film, it does not require otherwise limit the claim to this example. Importing limitations from the patent specification into the claims is not proper. *Phillips,* 415 F.3d at 1323; *see also Prima Tek II v. Polypap*, 318 F.3d 1143, 1151 (Fed. Cir. 2003). The claim and specification make clear that the digitized mammogram data need only have similar or analogous properties to the film images in the film technology, which were then being used by all radiologists. The Court should therefore adopt the USFRF's construction for these two terms, namely "*digital image presentations of a human breast*" in the event it decides to construe them.

Term 3: **"greyscale values"/ "grayscale values"[12]**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
No construction required. ***Alternatively,*** digital image luminance values corresponding to shades of grey from black to white	Numerical values representing a range of grays between white and black	Claims 1, 2, 3, 13, 14 and 17.

USFRF submits that these terms do not require construction separately from Term 11 above, and that their common and ordinary meaning in the digital imaging field is well known. (App.162-163, ¶ 61.) If a construction is needed, the terms simply mean: "*digital image luminance values corresponding to shades of grey from black to white*." (App.151, ¶ 29; App.162-163, ¶ 61.)

USFRF's proposed construction is supported by the claim language and the specification. First, the claims use "grayscale values" to refer to the "illuminate state" of the displayed image which can be controlled or adjusted by the user. (App.19, 9:13-14.) Specifically, Claim 1 recites "the illumination state corresponding to the grayscale values" thus making clear that these terms refer to varying the illumination state – not that the displayed images have a specific numerical grayscale value. (App.19, 9:7-8.) Independent Claims 2, 3 and 17 include similar language. (App.19, 9:51-54 (Claim 2), 9:66-10:2 (Claim 3), and 10:60-64 (Claim 17)).

Further, the specification makes clear that adjusting the grayscale value permits adjustment of the luminance or contrast of the image being viewed. (App.17, 5:39-41.) In use, the grayscale of an image can be adjusted between black which is at one end of the range, to white, which is at the other end of the range. (App.151, ¶ 29.) Indeed, "[t]he system comprises

[12] The alternate spellings of the color "gray" and "grey" is not significant as to the meaning or construction as they are used interchangeably in the art. (App.162-163, ¶ 61.)

means for establishing electronic communication with a processor for receiving a stored digitized medical image comprising data representative of a ***plurality of greyscale values***." (App.15, 2:17-20, (emphasis added); App.17, 5:39-51; App.4, FIG 3, step 308; App.5-9, FIGs 4-8.) Thus, the image data includes information representative of greyscale values in an x-ray film image such that the image data corresponds in character and quality to prior images and which may be adjusted to allow for improved and more accurate analysis. (App.147-153, ¶¶ 16-19, 24-32.)

Defendant proposes an erroneous construction requiring "numerical values" for the range of grayscale forms, which finds no support in the intrinsic evidence. Additionally, "numerical values" is not supported by extrinsic evidence, as it is not used in the digital imaging field. (App.161-163, ¶¶ 58, 61.) As used in the field, the term "grayscale values" refers to how the grayscale looks or appears to a radiologist. In use, persons do not refer to grayscale by a certain number, and do not utilize numerical readings or standards for selecting grayscale values. (App.161-163, ¶¶ 58, 61.) Much like adjusting the contrast of a television between the luminance of the brightest white and the darkest black that a TV can produce, there is no numerical value and any subsequent numerical value assigned would be irrelevant. (App.161-163, ¶¶ 58, 61.) The same applies for greyscale values here.

To the extent the Court construes these terms separately, they should mean: "*digital image luminance values corresponding to shades of gray from black to white*."

Term 4: **"Optical densities"**

Plaintiff's Proposed Construction	**Defendant's Proposed Construction**	**Claim(s) in which terms appear**
No construction required ***Alternatively,*** the degree of transparency of an analog image displayed on a	Numerical values representing the degree of blackness, or inability of light to pass through, a film	Claims 1 and 2

viewbox (aka a "light box")	image	

Again, like with Term 3 above, this term does not require construction separately from Term 11 above because its common and ordinary meaning in the digital imaging field is well known. (App.163, ¶ 62.) "Optical density" in the x-ray film field simply refers to the degree of transparency of an analog image when displayed on a viewbox (or "light box"). (App.153, ¶ 32.) As is known, film images have areas that allow light to pass, areas in which light is prevented from passing, and areas in which a certain amount of light can pass. (App.163, ¶ 62.) This is the context in which the claims and the specification use the term optical densities.

Like with "grayscale values," Claims 1 and 2 utilize "optical densities" to make clear that the "digitized mammogram image data" which comprises grayscale values, are of a quality, in terms of luminance as, the optical densities of a conventional film mammogram image. The invention was developed to maintain at least the same quality as film mammograms while realizing the benefits of digitization in terms of image storage and retrieval, image manipulation for display, and post display image manipulation. (App.16, 4:48-50; *see also* App.15, 1:65-67; App.16, 4:9-26, 4:36-46.)

Defendant, again seeks to limit the term by requiring the degree of transparency to a defined as precise "numerical" optical density value. Yet, nothing in the specification or other intrinsic evidence supports or requires such a limiting construction. Such a requirement also goes against the common meaning of "optical densities" as persons viewing an image on a light box do not consider anything numerical about the image or transparency. (App.163, ¶ 62.)

Thus, to the extent the Court construes this term separately from Claim 11, it should adopt USFRF's construction of: "the degree of transparency of an analog image displayed on a viewbox (aka a "light box")."

Term 5: **"plurality of varying resolution forms, each form having [different/a different set of] greyscale values"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
Multiple versions of the same image generated and displayed concurrently on different windows of a display monitor or monitors, each version having a different set of greyscale values and different resolution formats	Multiple versions of the same image generated and displayed concurrently on different windows of a display screen, each image version having a different range of grays between white and black represented by different numerical values	Claims 1, 3 and 17

Having withdrawn its erroneous assertion that this term is "indefinite," Defendant again seeks to impose a requirement that "varying resolution forms" have different ranges of grays, whites and blacks with concrete "numerical values." This term, as used in Claims 1, 3 and 17, simply refers to the system's ability to concurrently display images having varying greyscale values on a monitor for easy comparative viewing and diagnosis by a radiologist. USFRF's proposed construction accurately depicts the meaning of this term in the context of the '937 Patent and should be adopted. Specifically the specification provides:

> [t]he system comprises means for establishing electronic communication with a processor for receiving a digitized medical image comprising data representative of a ***plurality of greyscale values.*** … In addition, the software means comprises means for ***displaying the forms on the display means***, each form displayed within a different sector of the display means.

(App.15, 2:13-30, emphasis added.) Additionally, the specification also provides "FIGs 4-13 illustrate a ***series of digitized mammogram displays*** produced by the principles of the present invention…" (App.15, 2:51-56; App.4, FIG 3 step 308; App.17, 5:38-51.) Thus, the specification makes clear that this term references the ability of the data to be broken down into multiple images for easy analysis: "[i]n the analysis window, decimated views 41, 42 of the original

images are provided in the upper section (block 306). In the lower part two windows 43, 44 display selected sections (indicated by squares in the decimated views, block 307) at high resolution, i.e. from the original data." (App.17, 5:21-25.) Defendant's proposed construction is erroneous and inapplicable, at least, because it contains the same improper "numerical values" requirement it seeks to insert into Terms 3 and 4 above. As discussed, nothing in the '937 Patent indicates that numerical values are required – let alone even used – in practicing the interface system in the claims. (App.163, ¶ 63.) Defendant's proposed construction is an impermissible and unsupported attempt to generate a non-infringement argument, which should be rejected.

Term 6: **"predetermined illumination state"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
Plain and ordinary meaning: the greyscale values of a medical image established in advance for a window on a monitor	A range of grays between white and black established in advance for a version of an image and represented by different numerical values	Claims 1 and 2

Having also now withdrawn its meritless indefiniteness challenge to Term 6, Defendant again asserts that the construction of this term requires that the grayscale values be assigned "numerical values." Again, this assertion is flawed.

This term appears in context in the following limitation of Claim 1, which requires:

> means for communicating with a monitor to display the plurality of forms, each form within a different window on the monitor, and each form having a ***predetermined illumination state*** corresponding to the greyscale values thereof.

(App.19, 9: 3-7, emphasis added.) This term also appears twice in Claim 2 and although the wording is not exact, it is substantially the same and has the same meaning. (App. 19, 9:36-45.)

As with the terms disclosed above, the meaning of this term is clear to a POSA and was perfectly clear to the USPTO Examiner. (App.162-163, ¶¶ 58, 61.) More specifically, the USPTO Examiner stated:

> [T]he prior art of record . . . fails to teach or particularly suggest a system for providing an interface . . . [which includes] a monitor to display the plurality of forms, each form within a different window on a monitor, and each form having a **predetermined illumination state** corresponding to the grayscale values thereof.

(App.38.) The word "predetermined" means simply that the amounts of illumination (brightness) of the digital images in the monitor windows are established in advance. (App.164, ¶ 64.) Nothing in the specification or the file history requires numerical values.

Defendant's attempt to insert a "numerical value" into the claims should be rejected. The Court should adopt USFRF's proposed plain and ordinary meaning construction, "*the greyscale values of a medical image established in advance for a window on a monitor,*" which comports with the evidence of record.

Term 7: **"control the illumination state"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
Plain and ordinary meaning: the ability of a user to adjust the luminance of a displayed image on a monitor	Manually and dynamically adjust the numerical values for a range of grays between white and black in an image version	Claims 1 and 2

Put in context, Claim 1 incorporates the term "control the illumination state" as follows:

> means for receiving from the user communication means a control instruction for changing an illuminate state in a displayed form and for implementing the control instruction upon the displayed form, thereby permitting the use to ***control the illumination state*** of each displayed form.

(App.18-19, Claim 1, 9:9-14, emphasis added.) The language of Claim 2 is not exactly the same, but has the same meaning and context. (App.19, Claim 2, 9:46-54.)

As used in the claims, the meaning of this term is clear and unambiguous, and refers to the user's ability to control (such as by use of a mouse 10) the greyscale values of a digital image (luminance) in a window on the monitor screen. USFRF's proposed construction calls for exactly that ability and result.

Similar to the situation relative to Terms 5 and 6, Defendant seeks to import a requirement that the degree of brightness have specific numerical values. Again, the intrinsic evidence including the specification and the understanding by the USPTO Examiner demonstrate the flaws in Defendant's limiting construction. For example, the specification teaches that "one of the main features of the interface is the real-time greyscale adjustment" feature. (App.17, 5:39-40.) With this feature, the buttons (slide bars) 404-406 in the upper right-hand corner of Figure 4 are used (via a mouse) to control the greyscale values of the images in the windows of the monitor, each individually, in groups or all images at once. Nothing in the specification discusses a numerical values requirement. (App.161-163, ¶¶ 58, 61-63.) According to Dr. Samei, persons skilled in the art would understand that the control of the illumination state to mean the "ability of the operator to adjust the luminance setting of a display monitor," or "the ability of the user to adjust greyscale values of displayed image on a monitor." (App.164, ¶ 65.)

Accordingly, the Court should rejected Defendant's fifth attempt to improperly limit the claims to a "numerical value" when they can point to nothing in the intrinsic evidence justifying such a limiting construction, and adopt USFRF's proposed construction.

Term 8: **"to display a mammogram image in a different form in each window with grayscale values that, along with illumination characteristics of said monitor, appears to a user as a mammogram in each window under a predetermined illumination state"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
Capability to concurrently display on each window with grayscale values that, along with illumination characteristics of said monitor, appears to a user as a mammogram in each window under a predetermined illumination state	Indefinite Or Display concurrently on different windows of a display screen different image versions of a single mammogram image, each image version having a range of grays between white and black automatically assigned in advance to the image version and represented by different numerical values	Claim 2

This phrase is found only in Claim 2 and, when read in context, simply provides that the user of the patented interface have the ability to concurrently display digitized mammogram images in windows on a monitor, with each of the multiple images having illumination states (i.e. greyscale values) which are predetermined (established in advance). (App.19, 9:37-42.) For a better understanding, this term should be read with the proceeding term:

> said processor being adapted to receive signals from said input device, and being responsive to a signal from said input device to transfer digitized image data from said electronic storage medium to said monitor in a way that causes the monitor to produce a display having a plurality of windows and ***to display a mammogram image in a different form in each window with greyscale values that, along with the illumination characteristics of said monitor, appears to a user as a mammogram in each window under a predetermined illumination state*****,** thereby interfacing said mammogram image in each window and in a predetermined illumination state to an operator handling said input device.

(App.19, 9:32-45.) This allows the radiologist to use the mouse 10 (input device) to select digital mammogram images from storage and transfer them into different windows on a monitor with each image having different greyscale values (illumination states) determined in advance.

There is clear support for the term in the specification as well as the file history.

> Software means that are loadable into the processor comprise means for receiving a signal from a user-operable device and means controllable by a signal from the user-operable device for transforming the image into a plurality of varying-resolution forms, each form having a different set of greyscale values.

(App.15, 2:14-29; *see also* App.16, 4:40-5:7; App.17, 5:31-51.) The comments by the Examiner in the file history show that he fully understood the support, meaning and scope of this term. (App.38-40.) This is supported by the Declaration of Dr. Samei who states that a POSA, reading the specification of the '937 patent would understand the meaning and clarity of this term and construe it in the manner proposed by USFRF. (App.164, ¶ 66.)

Defendant initially contends that this term is indefinite, but has not provided any explanation for its assertion. Nonetheless, as evidenced by the specification as well as the testimony of Dr. Samei, the meaning of this term would be well understood by a POSA. *Nautilus, Inc. v. Biosig Inst., Inc.*, 572 U.S. 898 (2014) (*holding:* "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history fail to inform, with reasonable certainty, those skilled in the art about the invention.")

As for Defendant's alternative construction, it again requires importing the limitation that the grayscale values be represented ad "numerical values" in direct contraction to the way they are conventionally represented as understood by a POSA. (App.161-164, ¶¶ 58, 61, 66.) Defendant's indefiniteness assertion and alternative limiting construction should be rejected in favor of USFRF's proposed construction, which comports with the evidence of record.

Term 9: **"digital medical image"**

Plaintiff's Proposed Construction	Defendant's Proposed Construction	Claim(s) in which terms appear
Plain and ordinary meaning: an image of a portion of a human body in a digital format	Image of a patient's breast that has been produced by digitizing film of the breast image	Claim 3

This term appears in Claim 3, which recites as follows:

> means for establishing electronic communications with a processor for receiving a stored ***digitized medical image*** comprising data representative of a plurality of greyscale values.

(App.19, 9:57-60, (emphasis added.)) Like Terms 11 and 3 above, Defendant again improperly tries to import a requirement that "digitized medial image" originate from an x-ray film. This position is fundamentally flawed. First, the language of the claim broadly recites that the image comprises data with a plurality of grayscale values. Nothing in the claim limits – let alone even mentions – that the data must originate from any source. The specification similarly makes clear that the claims relate to a system that eliminates the need for film and is thus quicker to analyze, has improved flexibility and accuracy. Defendant's proposed construction utterly contradicts the fundamental teaching of the specification. The specification supports the broad usage of this term in claim, which should be defined as, "*an image of a portion of a human body in a digital format*." (App.165, ¶ 67.)

Defendant also seeks to limit the meaning of this term in another fashion. Specifically, despite the fact that the claim recites "**digitized medial image,**" Defendant asserts it only encompasses a "breast image." However, like the broad claim language, the specification discloses applying the inventive system to medical images beyond mammography. (App.16, 3:22-26.) Additionally, the claim differentiation doctrine renders Defendant's construction

untenable. Under this doctrine, if a term first expressly appears in a dependent claim, it is improper to limit the independent claim to require that term. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *see also Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 972 (Fed. Cir. 1999). Here, as the term "mammogram" is used expressly recited in dependent Claim 6. It would be improper to limit Claim 3 such that the medical image is "breast image" or mammogram.

Accordingly, Defendant's assertion that this term requires data originating from mammogram films is flawed and should be rejected. Instead, Plaintiff's proposed construction which tracks the intrinsic evidence and the meaning of this term to those of ordinary skill in the art should be adopted.

VI. THERE IS FULL SUPPORT FOR ALL OF THE MEANS-PLUS-FUNCTION TERMS

In an effort to denigrate the '937 Patented invention, Defendant has taken the erroneous position that none of the M+F terms in the claims have any support, making each and every claim indefinite. As stated by the Federal Circuit in *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003) (internal citation omitted), "[a] means-plus-function limitation recites a function to be performed rather than definite structure or materials for performing that function. Such a limitation must be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." If the words "means" or "means for. . ." are not used, then there is a presumption that the word is not subject to 35 USC §112 ¶6. *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880-881 (Fed. Cir. 2000).

Once a court establishes that a M+F limitation is at issue, it must identify and construe that limitation to determine what the claimed function is, and what structures are disclosed in the written description corresponding to the "means" for performing that function. *Lockheed Martin*

Corp., 324 F.3d at 1319. A M+F claim "shall be construed to cover the corresponding ***structure, material or acts*** described in the specification, or equivalents thereof," 35 U.S.C. §112(6); *Saffran v. Johnson & Johnson*, 712 F.3d 549, 561 (Fed. Cir. 2013) (emphasis added). Any structure disclosed in the specification is corresponding if it is linked or associated in any way to the function recited in the claim. *Chicago Board Options Exchange, Inc. v. International Securities Exchange, LLC*, 677 F.3d 1361, 1367 (Fed. Cir. 2012). The analysis of M+F claim elements and claims under 35 U.S.C. §112 ¶ 6 occurs through the eyes of a POSA. *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1378-79 (Fed. Cir. 1999) (The POSA's analysis "should apply in determining whether sufficient structure has been disclosed to support a means-plus-function limitation.")

Where the structure is a general purpose computer or microprocessor, "[r]equiring disclosure of an algorithm properly defines the scope of the claim and prevents pure functional claiming." *See Ergo Licensing, LLC v. CareFusion 303, Inc.*, 673 F.3d 1361, 1364 (Fed. Cir. 2012). An "algorithm" is "a step-by-step procedure for accomplishing a given result," and may be expressed "in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure." *Id.* at 1365 (citations and internal quotation marks omitted). In software cases, "algorithms in the specification need only disclose adequate defining structure to render the bounds of the claim understandable to one of ordinary skill in the art." *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1245 (Fed. Cir. 2007) (internal citations omitted). The supporting structure, materials, acts or algorithm can be found by a combination of a flow chart or a Figure when combined with written portions ("prose") of the specification. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323,

1341 (Fed. Cir. 2008). The knowledge of a [POSA] can be used to make clear how to implement a disclosed algorithm. *Intel Corp. v. VIA Techs.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003)

Defendant has proposed ten M+F terms which it asserts do not have any support in the '937 Patent. Specifically, despite a wealth of evidence, the Defendant disingenuously argues that there is not a single reference to any ***structure, material or acts*** to support even one of the claimed functions. Additionally, Defendant also appears to assert that the '937 Patent fails to disclose an algorithm to perform the recited functions. USFRF takes this challenge head on and provides specific and detailed references to the disclosure pointing out and explaining the structure, material or acts that support respective function for each of the ten terms. In order to preserve space, USFRF incorporates Appendix B of the Joint Claim Construction statement, which contain additional citations to disclosure in the specification corresponding to the claimed "means" which set forth in detail the numerous instances of support on the specification for the M+F terms.[13]

In addition to the intrinsic evidence, USFRF's positions are supported by Mr. McAlexander, a well-respected expert who has opined that none of the 10 terms are indefinite and a POSA would understand the structure, materials, or acts in the patent specification which are linked to the function of each of the terms. USFRF's intrinsic and extrinsic evidence is more than sufficient to show definite means meeting the requirements of 35 U.S.C. §112 ¶ 6.

> ***Term 12:*** **"means for transforming the digitized mammogram data into a plurality of varying-resolution forms, each form having different greyscale values" (Claim 1)**

The parties agree Term 12 is a M+F term with a function of "transforming the digitized mammogram data into a plurality of varying-resolution forms, each form having different

[13] For the Court's convenience, Appendix B from the Joint Statement is submitted herewith as App.115-142.

greyscale values." The parties dispute whether the specification provides corresponding structure to perform the claimed function.

Defendant asserts that no corresponding structure is identified in the specification and this "means" term is indefinite. This is erroneous. The corresponding structure includes the workstation processor 10 (Ultra SPARC2200 systems), as exemplarily shown in Figures 1 and 2, which executes one or more instructions stored on a computer-readable storage medium of the workstation. (App.16, 3:37-50; App.3, FIGs 1-2.) The workstation processor 10 executes the instructions for performing the processing algorithm of Figure 3. (App.2, Abstract; App.3-4, FIGs 1-3; App.16, 3:45-48). In other words, the structure of a special purpose computer programmed to carry out the disclosed algorithm satisfies the structural requirements of Section 112, ¶ 6. *See Aristocrat Tech Australia Pty Ltd. v. Int'l Frame Technology,* 521 F.3d 1328, 1338 (Fed. Cir. 2008).

The exemplary steps of the algorithm relative to this function are also specifically set out in steps 304 – 306. These disclosed steps include changing the pixel sizes of binary information to form a plurality of varying forms each with different greyscale values. (App.15, 2:14-27; App.4, FIG 3.) Specifically with reference to the '937 Patent and Figure 3, steps 304 – 306 of the processing algorithm loads the set of original images (step 304), converts the images from 16 bit to 8 bit for display on the monitor (step 305), and then creates the smaller "decimated" views (step 306). (App.17, 5:14-28.) Thus, the digitized mammogram data is transformed into a plurality of varying-resolution forms. The '937 Patent further explains the results of these steps as follows:

> When ready, the observer can proceed to the analysis part of the interface, which replaces the global views by a window 40 shown in FIG. 4 (one per monitor; blocks 304,305), containing, e.g., left 41 and right 42 CC views. The radiologists

> are always able to go back to the global overview (button 401) and look at the case at a glance.
>
> In the analysis window, decimated views 41, 42 of the original images are provided in the upper section (block 306)

(App.17, 5:14-23.) These lower resolution decimated views 41, 42 can be displayed concurrently with a higher resolution image of step 308. (App.17, 5:23-28.) Each image can be individually adjusted, including greyscale values, controls of which are shown in the top right corner of Figure 4 (App.17, 5:39-51.) The image manipulation software to run the routines are also specifically identified and included in the XIL imaging library and Motif tool kit (App.16, 4:27-35.)

Mr. McAlexander agrees that the supporting structure above provides sufficient support for this M+F term. (App.310-311, ¶ 7.5.3.1.) Mr. McAlexander declares that a POSA at the time of the invention would have been informed how to implement the corresponding structure for "transforming the digitized mammogram data into a plurality of varying-resolution forms, each form having different greyscale values." (App.310-311, ¶ 7.5.3.1.) In short, the '937 Patent discloses sufficient means to transform the digitized mammogram data into a plurality of varying-resolution forms, each form having different greyscale values as required by Term 12 and it is not indefinite.

> ***Term 13:*** **"means for communicating with a monitor to display the plurality of forms, each form within a different window on the monitor, and each form having a predetermined illumination state corresponding to the greyscale values thereof" (Claim 1)**

The parties agree Term 13 is a M+F term having a function of "communicating with a monitor to display the plurality of forms, each form within a different window on the monitor, and each form having a predetermined illumination state corresponding to the greyscale values thereof." Again, the parties dispute whether the specification provides sufficient support of the means to perform this function.

The corresponding structure is the workstation processor 10 (Ultra SPARC2200 systems), exemplarily shown in Figures 1 and 2, which executes one or more instructions stored on a computer-readable storage medium of the workstation. As disclosed, the workstation processor 10 executes the instructions to perform the processing algorithm of Figure 3, for example, Step 308 to achieve the function of Term 13. (App.4, FIG. 3; App.16, 3:45-48.)

The exemplary steps of the algorithm relative to this function are also specifically set out in Step 308 which creates an analysis window having all four views ready for display, including adjustments to the greyscale using button 402. Each form (image) has a different set of grayscale values. (App.15, 2:22-27.) Each image can be individually adjusted, including their grayscale values, to display different illumination states to allow for improved diagnostics. (App.17, 5:39-51.) This principle is evident in FIGs. 4 – 13 showing the various illumination states:

> FIGS. 4-13 illustrate a series of digitized mammogram displays produced by the principles of the present invention, in various states of illumination, and also how various features of the present invention are displayed and can be used by a radiologist in examining a digitized mammogram produced by the system of the present invention.

(App.15, 2:51-56.) Specifically, FIG. 5 illustrates greyscale adjustment on a single image. (App.15, 2:58.)

POSAs at the time of the invention would thus have been informed from the standpoint as to how to implement the corresponding structure to perform the claimed function – namely a computer with imaging software or equivalents thereof. (App.312-313, ¶ 7.5.3.2). The Defendant alleges that no corresponding structure is identified in the patent specification. This is erroneous and disingenuous and Defendant's indefiniteness challenge should be rejected.

Term 14: **"means for receiving from the user communication means a control instruction for changing an illumination state in a displayed form and for implementing the control instruction upon the displayed form, thereby permitting the user to control the illumination state of each displayed form" (Claim 1)**

The parties only dispute with respect to Term 14 is whether there is sufficient means to support the agreed upon function of a "receiving from the user communication means a control instruction for changing an illumination state in a displayed form and for implementing the control instruction upon the displayed form, thereby permitting the user to control the illumination state of each displayed form."[14] Summarily, there is more than sufficient structure in the '937 Patent to defeat the Defendant's weak indefiniteness argument.

The corresponding structure for Terms 12 and 13 also provides some of the support for Term 14. Specifically, the corresponding structure is the workstation processor 10 (Ultra SPARC2200 systems), exemplarily shown in Figures 1 and 2, which receives control instructions through a device (from e.g. a mouse 18) by selection of one or more of buttons 402, and 404 – 406. (App.3, FIG. 2; App.16, 3:45-48, 4:66-5:1; App.17, 5:39-44; 6:7-12.)

The exemplary steps of the algorithm relative to this function are also specifically set out in the specification. The user selection is then read by the workstation processor 10 executing the control instruction at step 308 of FIG. 3 (XIL Image Library), causing the generation of instructions to control illumination via changing of the greyscale values. (App.2, Abstract; App.15, 2:20-30; App.17, 5:14-17; *see also* App.16, 4:28-32; App.5-6, FIGs 4-5). USFRF's recitation of the structure is supported by its expert. (*See* App.313-314, ¶ 7.5.3.3.)

[14] For clarity, Plaintiff further defines user communication as a "user I/O device."

> ***Term 15:*** **"said processor. . . being responsive to a signal from said input device to transfer digitized image data from said electronic storage medium to said monitor in a way that causes the monitor to produce a display having a plurality of windows and to display a mammogram image in a different form in each window with grayscale values that, along with the illumination characteristics of said monitor, appears to a user as a mammogram in each window under a predetermined illumination state" (Claim 2)**

The parties disagree whether Term 15 is subject to 35 U.S.C. §112 ¶ 6. As seen above, the term does not use the magical language "means" and thus there is a presumption that the term is not a M+F term. *Watts*, 232 F.3d at 880-881. This presumption can only be rebutted by showing that the claim element recited a function without reciting sufficient structure for performing that function. *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999) (explaining the converse rules for rebutting a presumption that §112, ¶ 6 does apply).

Tellingly, Claim 2 places direct structural limitations on the processor. Specifically, the processor is in "circuit communication with said monitor and said electronic storage medium" and an input device is "in circuit communication with said processor." Clearly, the structural connection of the claimed processor to an input device allows the processor to receive various inputs; and structural connection of the claimed processor to a storage device and to a monitor allows the processor to store and retrieve data to/from the storage device and to display data retrieved onto a monitor.

Defendant also fails to consider that the two primary parts of Claim 2 state the "processor being adapted" – "to receive input signals from said input device" and "to transfer digitized image data from said electronic storage medium to said monitor." A POSA would understand that uncontested structures – a processor, an input device, a storage medium, a monitor, and the connections between them – already appear in the claim. (App.314, ¶ 7.5.3.4.)

As Defendant cannot overcome the presumption, this term is not subject to 35 U.S.C. § 112 ¶ 6 and therefore does not require construction. Accordingly, the specification supports the structures mentioned in this term. To the extent, the Court determines that this term is governed by § 112 ¶ 6, it is not indefinite, as the specification again contains clear structure as well as an algorithm for performing the claimed function. This structure is set forth in the Joint Claim Construction Statement. (App.123-128.)

> ***Term 16:*** **"said processor being adapted to receive further input from said input device related to the mammogram image in a selected window, said further input from said input device including input that selectively controls the grayscale values of the mammogram image in the selected window, thereby enabling an operator handling said input device to selectively control the illumination state with which the mammogram image in the selected window is displayed to the operator" (Claim 2)**

For many of the same reasons set forth above, Term 16 is also not a M+F term, and should not be construed under the guidance of Section 112, ¶ 6. Again, the claim language makes clear that the processor is in "circuit communication with said monitor and said electronic storage medium" and an input device is "in circuit communication with said processor." Clearly, the structural connection of the claimed processor to an input device allows the processor to receive various inputs, and the structural connection of the claimed processor to a storage device and monitor allows the processor to store and retrieve data to/from the storage device and to display data retrieved onto a monitor.

Defendant ignores these claimed structures and connections and instead contends that, even with the absence of "for" or "means for," the phrase surrounding "said processor" falls under 35 U.S.C. §112, ¶ 6. The primary part of this phrase states the "processor being adapted to receive further input from said input device." The uncontested structures – a processor, an input device, a storage medium, a monitor, and the connections between them – are specifically

identified in the claim. This additional language, purported by Defendant as falling within the function of a M+F term, merely states what transpires between the structures to achieve the results claimed. (App.317-319, ¶ 7.5.3.5.)

As Defendant cannot overcome the presumption, this term is not subject to 35 U.S.C. §112, ¶ 6, and does not require construction. The '937 Patent specification the supports the structures mentioned in this term. To the extent, the Court determines that this term is governed by Section 112 ¶ 6, it is not indefinite, as the specification again contains clear structure as well as an algorithm for performing the claimed function. This structure is set forth in the Joint Claim Construction Statement. (App.123-133.)

> ***Term 17:*** **"means for establishing electronic communications with a processor for receiving a stored digitized medical image comprising data representative of a plurality of greyscale values" (Claim 3)**

The parties dispute whether there is a sufficient structure in the specification for the claimed function of, "establishing electronic communications with a processor for receiving a stored digitized medical image comprising data representative of a plurality of greyscale values." Contrary, the Defendant's assertion, the '937 Patent contains sufficient structure to meet the requirements of §112, ¶ 6, and the claim is not indefinite.

The '937 Patent specification details the "user input device(s)" such as a mouse or keyboard, to communicate with the processor for receiving the stored digital images. (App.15, 2:17-19.) The mouse 18 or keyboard is used to select a menu. (App.16, 4:64-5:2; App.4, FIG. 3, steps 301, 302, 303 and 304.) Once a selection is made, the processor 10 responds to that user selection input by executing the instructions that correspond to the selection, such as loading preview selection 302 from the image storage data 12 and displaying a full size image overview 303 which is shown in FIG. 3. (App.16, 3:6-4:3; App.17, 5:7-14; App.18, 7:3-10.) The disclosure of the algorithm is sufficient to allow a POSA to implement the corresponding structure in the

specification to establish electronic communications with a processor for receiving a stored digitized medical image. (App.319-320, ¶ 7.5.3.6.) The term is thus not indefinite and there is both structure in the specification corresponding to the claimed means, including a software algorithm.

Term 18: **"means for receiving a signal from a user-operable device" (Claims 3, 17)**

Again, while Defendant contends that this term is indefinite as there is no structure disclosed in the specification corresponding to the claimed means, the '937 patent clearly teaches sufficient structure for performing the claimed function. Specifically, the specification teaches a workstation processor 10 (Ultra SPARC2200 systems), shown in Figures 1 and 2, for executing instructions to perform the disclosed algorithm. According to the disclosed algorithm, the processor receives control instructions through a device (from e.g. a mouse 18). (App.3, FIGs 1, 2; App.16, 3:45-48, 4:66-5:1; App.17, 5:39-44, 6:7-12.) The control instructions are sent by the user and read by the workstation processor 10 executing the control instruction at Step 308 of FIG. 3 (XIL Image Library), performing the processing algorithm. (App.16, 4:28-33, 4:64-5:2; App.17, 5:29-32, 5:39-44.) The specification clearly discloses the use of software and an explanation how it is used to receive signals from an I/O device in order for a user to display and manipulate images. (App.321, ¶ 7.5.3.7.) Accordingly, Defendant's assertion that Term 18 is indefinite is erroneous.

Term 19: **"means controllable by a signal from the user-operable device for transforming the image into a plurality of varying-resolution forms, each form having a different set of greyscale values" (Claims 3, 17)**

Contrary to Defendant's assertions, there is structure and material disclosed in the specification corresponding to the claimed means for "transforming the image into a plurality of varying-resolution forms." As set forth repeatedly above, the workstation processor 10, when

executing the user's instructions, performs the processing algorithm of Figure 3, thereby changing the pixel sizes of binary information to form a plurality of varying forms each with different greyscale values based on signals from user input devices. Steps 304-306 of the algorithm disclosed in Figure 3 together with prose in the specification, show how the user can use the input device to transform the image into a plurality of varying resolution forms with different grayscales. (App.4, FIG. 3; App.15, 2:20-27; App.17, 5:21-28.) Specifically, the algorithm dictates that, a set of original images are uploaded to the system (step 304), the images are then converted from 16 bit to 8 bit for display on the monitor (step 305), and the smaller "decimated" views are created (step 306). (App.4, FIG. 3; App.15, 2:20-27; App.17, 5:21-28.) Thus, in this 3-step process, the digitized mammogram data is transformed into a plurality of varying-resolution forms. These decimated views 41, 42 are lower resolution images that can be displayed concurrently with a higher resolution image of step 308. (App.17, 5:25-28.) According to the specification, each image can be individually adjusted, including greyscale values, controls of which are shown in the top right corner of Fig. 4. (App.17, 5:39-51.)

Mr. McAlexander agrees that this support constitutes the structure, material and acts and as required by § 112 ¶ 6 is the means for this M+F term. (App.310-311, ¶ 7.5.3.1.) As such, Defendant's assertion of indefiniteness should be rejected.

Term 20: **"means for displaying the forms on the display means, each form displayed within a different sector of the display means" (Claim 3)**

Again, contrary to the Defendant's indefiniteness argument, the '937 specification provides sufficient structure, material, or acts the functions for "displaying the forms on the display means (*e.g.*, monitors), each form in a different sector (window)."[15]

[15] The functions submitted by the parties are not identical, but are principally the same. Plaintiff's construction provides examples of display means (*e.g.*, monitors), and sectors

As set forth repeatedly above, the workstation processor 10 when executing the user's instructions, performs the processing algorithm of Figure 3, step 308, causing the display of binary information in different spatial resolutions in different monitor windows 16. (App.3-4, FIGs. 1-3; App.15, 2:27-30; App.16, 4:24-26; App.17, 5:21-28.) Specifically, the algorithm dictates that decimated views 41, 42 are lower resolution images that can be displayed concurrently with a higher resolution image of step 308 at two lower windows. (App.17, 5:25-28, 6:7-12.) The algorithm also allows for various modifications, including greyscale value adjustments (step 308) wherein the changes can be made in one of the smaller windows, which is then transmitted to selection section windows and applied to all 4 windows on both monitors 14, 16. (App.4-10, FIGs. 3-9; App.17, 5:44-47.) This identical structure is also discussed above with the Terms 13, 14, and 18 that relate to the displaying step 308 of the Fig. 3 algorithm.

The structure and the algorithm disclosed provide a POSA sufficient means to "display[] the forms on the display means (*e.g.*, monitors), each form in a different sector (window)." (App.322-323 ¶ 7.5.3.9; *see also* App.312-317, ¶¶ 7.5.3.2, 7.5.3.3, and 7.5.3.4.) The claim is thus not indefinite.

***Term 21:* "means for displaying a first form on the first monitor and a second form on the second monitor (Term 21 in Claim 17)"**

The Defendant erroneously contends that the specification does not identify any corresponding structure allowing for "displaying a first form on the first monitor and a second form on the second monitor." Specifically, the '937 Patent specification identifies monitors 14 and 16 in FIGS. 1 and 2. Once images are loaded, an initial image (full-size) is displayed at step 303 of the Figure 3 algorithm on one of the two monitors and an ML (left and right medio-

(window), and should be adopted as it better informs one of ordinary skill in the art at the time of the invention of an example of a display means and correlates sector to a window of a display.

lateral) image is displayed on the other. (App.17, 5:7-13.) As stated in the specification, one of the steps in the Figure 3 algorithm is to display the CC views "on one of the two monitors" of the workstation and the "ML views on the other monitor." (App.17, 5:9-12.) Global views can then be replaced at steps 304-305 of the Figure 3 algorithm with a window 40 shown in FIG. 4. (App.17, 5:14-18.) The claim is definite. (App.323-324 Decl. ¶ 7.5.3.10.)

VII. CONCLUSION

For the foregoing reasons, USFRF respectfully requests that the Court adopt its proposed constructions of the disputed terms contained in the asserted claims.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was filed electronically and served on all counsel of record on September 17, 2018 via the Court's ECF system.

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